Exhibit “S”

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2419** **Dkt. No. 1:13-md-2419-RWZ**
This Document Relates to Suits Naming:	)	
All Cases Pending Against Saint Thomas Outpatient Neurosurgical Center And Related Defendants	)	

PLAINTIFFS' SECOND SUPPLEMENTAL RESPONSE TO SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC; HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION; JOHN W. CULCLASURE, MD; AND DEBRA V. SCHAMBERG, RN, FIRST INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS PROPOUNDED TO THE PLAINTIFFS

Pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and Judge Boal's September 8, 2015 order (Dkt. No. 2224), the Plaintiffs' Steering Committee hereby serves these supplemental responses to the First Interrogatories and Requests for Production Propounded by the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Clinic"), Howell Allen Clinic, John W. Culclasure, MD, and Debra V. Schamberg, RN (collectively "Defendants" or "Saint Thomas Clinic Defendants").

INSTRUCTIONS AND DEFINITIONS AND OBJECTIONS

1. The term "Plaintiffs" shall mean all Plaintiffs who have pending cases against any of the Saint Thomas Clinic Defendants in active cases in the MDL.

2. The term "Plaintiffs' Counsel" shall mean the Tennessee State Chair as designated by Plaintiffs' Steering Committee pursuant to MDL Order No. 2.

3. The term "MDL" shall mean the multidistrict litigation *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL 2419, currently pending before Judge Rya Zobel in the United States District Court for the District of Massachusetts.

4. The following responses are meant only to apply to cases pending in the MDL against the Saint Thomas Clinic Defendants and are not intended to be nor should they be considered to bind or apply in any other case pending in the MDL.

5. Many of the following requests require production of documents exchanged as part of the mediation program created by MDL Dkt. No. 394 (the "Mediation Order). The Mediation Order specifically states that any such information exchanged during mediation is confidential and not subject to production. Accordingly, Plaintiffs' Counsel will refuse to produce any documents or information obtained as part of the mediation program in accordance with the clear directives of the Court's Mediation Order.

6. Many of the following Interrogatories include numerous sub-parts, well over the forty permitted under the Court's MDL Order No. 9, Dkt. No. 1425 (the Common Discovery Order"). In a show of good faith in an attempt to cooperate with the orderly administration of common discovery, Plaintiffs Counsel will answer all Interrogatories posed, but will reserve the right to refuse to answer any additional Interrogatories beyond the forty permitted by the Common Discovery Order.

7. Plaintiffs maintain a standing objection to the Instructions and Definitions propounded as part of the Saint Thomas Clinic Defendants' discovery responses to the extent that those Instructions and Definitions are beyond the scope of the Federal Rules of Civil Procedure.

INTERROGATORIES

1. If the Plaintiffs' response to any of these Defendants' First Requests for Admissions propounded to the Plaintiffs is anything other than an unqualified admission, for each such Request for Admission, state (with identification of the corresponding Request for Admission):

   (a) All facts (not opinions) that the Plaintiffs contend support the denial or qualification of the admission.

   (b) By Bates number, if applicable, all documents, electronic and/or tape recordings, photographs, oral statements, or any other tangible or intangible thing that supports the denial or qualification of the admission.

   (c) The name and address of the custodian of all tangible things identified above.

   (d) The name and address of all persons, including consultants and experts, purporting to have knowledge or factual data upon which the Plaintiffs base the denial or the qualification of the admission.

ANSWER:

Plaintiffs object to this request as it is overly broad and unduly burdensome, and it requests information protected by the work product doctrine. These Defendants served 142 requests for admissions. Information supporting any denials of those requests is contained in Plaintiffs responses to those requests. Those responses are incorporated herein by reference.

First Supplemental ANSWER:

This supplemental answer is limited to explaining the denial of Requests for Admission Numbers 1 and 2 per Judge Boal's September 8, 2015 order. Plaintiffs incorporate by reference their responses to RFAs 1 and 2 into their response to Interrogatory 2. Plaintiffs further state that HCPCS J1040, J1020 and J1030 could be used to bill for the steroid injection; however, Plaintiffs believe that some (if not most) third-party payors would not separately reimburse for these codes. In fact, in the 2012 ambulatory surgery fee schedule, Medicare (which many third party payors follow) indicates that these codes are "packaged service/item; no separate payment made."[1] As such, Defendants would have no reason to bill for these codes since the cost of the steroid would need to be covered in what third-party payors would actually reimburse. Based on the limited review of documents presently available to Plaintiffs' Counsel, in this case, the facility fee would cover the steroid administered to patients as this fee covers "drugs and biologicals for which

[1] This publicly available document is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

separate payment is not made under the OPPS [CMS' Outpatient Prospective Payment System], surgical dressings, supplies, splints, casts appliances, and equipment."[2]

2. Does the PSC know of any purchaser or potential purchaser of pharmaceutical products from NECC who performed any of the due diligence the PSC alleges in paragraph 193 of the Master Complaint (reproduced below) was required before purchasing? If so, (1) identify the purchaser or potential purchaser, (2) describe the date of all due diligence, and (3) the content of the due diligence activities, conducted by each purchaser or potential purchaser.

Paragraph 193 alleges the following due diligence was required:

a) verify whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

b) determine if NECC was an accredited compounding pharmacy;

c) at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff;

d) determine whether NECC had any product liability lawsuits filed against it for preparations compounded;

e) determine whether there had ever been recalls of any of NECC's compounded preparations;

f) evaluate NECC's standard operating procedures and manuals;

g) evaluate NECC's pharmacist technician training;

h) evaluate NECC's policies and procedures for sterility testing;

i) evaluate examples of batch reports for product being considered for outsourcing;

j) evaluate examples of quality-control reports;

[2] This publicly available document is located at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AmbSurgCtrFeepymtfctsht508-09.pdf<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AmbSurgCtrFeepymtfctsht508-09.pdf>.

k) obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l) determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pathogens and unintended particulate matter;

m) evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n) determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o) determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p) determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability;

q) determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r) evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s) evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; and

t) determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER:

Plaintiffs object to this Interrogatory to the extent that it seeks to obtain information from consulting experts or information protected by the work product doctrine. Plaintiffs are not required to disclose the opinion of any consulting or non-disclosed expert witness at this time. Plaintiffs further object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). *See e.g., In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992).

FIRST SUPPLEMENTAL ANSWER:

Plaintiffs have not done an exhaustive review of all potential healthcare providers who performed some due diligence before purchasing from NECC, but the document and information presently available to the Plaintiffs reveals that the following medical providers performed sufficient due diligence prior to purchasing from NECC to learn that it was not safe or advisable to purchase from NECC as gleaned from the documents produced by NECC as part of this litigation:

Orthopedic Clinic of Daytona Beach
1075 Mason Ave.
Daytona Beach, FL 32117

Central Indiana Orthopedic Center
2610 Enterprise Drive
Anderson, IN 46013

New Hope Orthopaedics & Sports Medicine
13421 Old Meridian St., Suite 202
Carmel, IN 46032

Saddle Brook Surgical Center
444 Market Street
Saddle Brook, NJ 07633

Dr. John S. Rollins, MD
2505 Samaritan Dr.
San Jose, CA 95124

LSC Orthopaedics Sports Medical Center
955 Lane Ave., Suite 200
Chula Vista, CA 91914

Las Vegas Pain Institute and Medical Center
3 locations: **7175 N. Durango Drive, Suite 220**
Las Vegas, NV 89149

Nellis Medical Center
1900 N., Nellis Blvd.
Las Vegas, NV 89115

Las Vegas Medical Center
3835 South Jones Blvd., Suite 104
Las Vegas, NV 89103

Aiken Regional Medical Center
302 University Parkway
Aiken, SC 29801-1117

Excelsior Orthopaedics
3925 Sheridan Dr.
Buffalo, NY 14226

Heekin Orthopedic Specialists
10475 Centurion Pkwy N
Ste. 220
Jacksonville, FL 32256

Bellevue Hospital Center
462 1st Ave.
New York, NY 10016

Palm Beach Spine and Pain Institute
2290 10th Ave. N., #600
Lake Worth, FL 33461

UAB Callahan Eye Hospital
1720 University Blvd.
Birmingham, AL 35233

Outpatient Services East
52 Medical Plaza Dr. #401
Birmingham, AL 35235

Promise Regional Medical Center
1701 E. 23rd Ave.
Hutchinson, KS 67502

South Georgia Medical Center
2501 N. Patterson Street
Valdosta, GA 31602

Greenwood OB/GYN
106 Liner Dr.
Greenwood, SC 29646

Belleair Surgery Center
1130 Ponce De Leon Blvd.
Clearwater, FL

Orlando Center for Outpatient Surgery
1405 S. Orange Ave.
Orlando, FL 32806

The scope and extent of the above-identified due diligence efforts, to the extent known to Plaintiffs' counsel, is revealed in the documents produced by NECC in this litigation and Plaintiffs' Counsel incorporates by reference the business records identified in Interrogatory No. 3 into its response to this Interrogatory.

Further, as made clear by the deposition of Martin Kelvas and Terry Grinder, Saint Thomas Hospital and Saint Thomas Health, through a simple phone call to the Tennessee Department of Health, confirmed that it was illegal to purchase drugs, in bulk and without prescriptions, from NECC in the manner in which the Saint Thomas Clinic purchased from NECC.

3. Identify the source(s) of the information provided in response to Interrogatory 2, including contact information for any individual and the location and Bates number(s) of any documents or electronically-stored information.

ANSWER:

See response number 2 above.

FIRST SUPPLEMENTAL ANSWER:

Plaintiffs' Counsel identifies the following documents currently located on the US Legal Repository for the MDL:

NECC_MDL 24334-24337
NECC_MDL 38141
NECC_MDL 49917
NECC_MDL 38095
NECC_MDL 34291
NECC MDL 48344
NECC_MDL 39276
NECC_MDL 45470
NECC_MDL 34325
Medical Sales Management 439-440
OCOS 175-189.

Plaintiffs' Counsel also identifies the deposition testimony of Martin Kelvas and Terry Grinder.

8. Identify all compounding pharmacies or FDA-registered manufacturers of Depo Medrol or its generic equivalent that were producing Depo-Medrol or its generic equivalent from January 2011 to October 2012 to support the allegation that these Defendants could and/or should have purchased from another compounder or an FDA-registered manufacturer. For each compounder or manufacturer, identify the timeframe of the availability of the Depo-Medrol or its generic equivalent, the price of the Depo-Medrol or its generic equivalent during the timeframe of availability, and any distributor or supplier selling the Depo-Medrol or generic equivalent to healthcare providers during the timeframe of availability.

ANSWER:

Plaintiffs object to this Interrogatory to the extent that it seeks to obtain information from consulting experts or information protected by the work product doctrine. Plaintiffs are not required to disclose the opinion of any consulting or non-disclosed expert witness at this time and will do so in accordance with Rule 26 and the Court's Common Discovery Order. Plaintiffs further object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). *See e.g., In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992). Plaintiffs object to this Interrogatory in that it requires Plaintiffs to review documents and statements made by Defendants. As such, discovery over the information sought by this Interrogatory can be obtained from some other source that is more convenient, less burdensome, and/or less expensive than requested, namely Defendants can review their own statements or admission in their own documents and from its own employees and agents. Accordingly, the information requested by this Interrogatory is beyond the scope of permissible discovery under Fed. Rule Civ. P. 26(b)(2)(C)(1). *See e.g. DiNapoli v. Int'l Alliance of Theatrical Stage Employees 8*, Civ. Action No. 09-5924, 2011 U.S. Dist. LEXIS 27895, 2011 WL 1004576, at *7 (E.D. Pa. Mar. 18, 2011).

Subject to and without waiving these or any other objection, photographs taken by Saint Thomas Clinic in 2012 inside the clinic show storage cabinet drawers stocked with Depo-Medrol made by Pfizer.

SUPPLEMENTAL ANSWER:

It was illegal or unlawful for a compounding pharmacy to manufacture and sell Depo-medrol or its generic equivalent. Plaintiffs are unaware of any other compounding pharmacy that acted in the same manner as NECC. Plaintiffs' Counsel has not undertaken an exhaustive survey of the hundreds of compounding pharmacies across the country to determine whether such pharmacies compounded MPA during the identified time period. Plaintiffs' Counsel is aware that Teva Pharmaceutical Industries Ltd., Sandoz Inc., and Pfizer Inc. manufactured MPA during the relevant time period.

MPA in its generic or brand name forms was readily available during 2011-2012 from a variety of wholesalers/distributors including but not limited to Clint Pharmaceuticals, PSS World Medical, Inc., Curascript, and Besse Medical.

11. Identify all information about NECC that the Plaintiffs contend the Defendants were required to obtain via the allegedly required minimum due diligence and describe in detail where the information was available, the reasonable steps necessary to obtain or locate it, and the basis for the Plaintiffs' belief that the information could have been obtained or located.

ANSWER:

Plaintiffs object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). *See e.g., In re eBay Seller Antitrust Litig.,* Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group,* 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson,* 143 F.R.D. 93 (E.D. Pa. 1992).

FIRST SUPPLEMENTAL ANSWER:

Plaintiffs identify the following information:

The fact that NECC was a compounding pharmacy was sufficient to alert Defendants that NECC was not an appropriate supplier of MPA. Defendants should have learned from a reasonable search that it was illegal under Tennessee law to order compounding pharmaceuticals in bulk and without patient specific prescriptions. A simple phone call to the Tennessee Department of Health would have revealed this to the Defendants. Further, a simple review of the licensure status of NECC should have alerted Defendants to NECC's illegal activity in Tennessee. Specifically, NECC was licensed as a pharmacy in Tennessee and not as a wholesaler or manufacturer of pharmaceuticals. This placed NECC within a different regulatory regime triggering the patient-specific requirement as readily admitted by Saint Thomas Hospital's Pharmacy Director, Martin Kelvas in his deposition.

Similarly, a simple call to the Massachusetts Board of Pharmacy would have revealed that NECC was prevented under Massachusetts law from fulfilling orders without patient-specific prescriptions, and Ms. Schamberg was alerted to this fact when NECC's representative began requesting individual patient names in the summer of 2012. This should have raised red flags about the Defendants' continued relationship with NECC, red flags that the Defendants simply ignored and instead, in some instances, decided to falsify order forms in lieu of complying or even investigating the applicable law.

Additionally, the Defendants could have easily requested from NECC the sterility testing it ordered from its third-party testing agency. NECC made these testing results readily available to any customer who asked (for those ordering online it was as simple as checking a box). By doing this simple task, the Defendants would have learned that NECC failed to obtain sterility testing for the final product that it was sending to the Defendants. This would have been yet another red flag that NECC's activities were unsafe and specifically not in compliance with USP 797.

Had Defendants also conducted a timely and thorough site visit and full USP 797 audit of NECC and its facilities, Defendants would have learned of the following:

a. **NECC was not accredited by the Pharmacy Compounding Accreditation Board (McAteer Dep: 219-220);**
b. **NECC was not trending or tracking sterility and endotoxin results (McAteer Dep: 226);**
c. **NECC had settled a product liability case after a man died from a steroid injection of NECC products (McAteer Dep: 227);**
d. **NECC would not let them into clean rooms to inspect the compounding process used by NECC. (McAteer Dep: 202-205);**
e. **NECC was not submitting sufficient samples to ARL for sterility testing pursuant to USP 71; (*See e.g.* Dep. Ex. 516-10; 54-56);**
f. **NECC was not submitting true "final product" for endotoxin and sterility testing to ARL for final testing (*See e.g.*, Dep. Ex. 516-10; 54 -56);**
g. **NECC was not properly autoclaving and following its NECC SOPs on autoclaving as shown by the Logged Formula Worksheets;**
h. **NECC had not audited ARL for its compliance with USP 71 and 797 (McAteer Dep: 213)**
i. **NECC would not have allowed Defendants to review compliant files maintained by NECC (McAteer Dep: 269-270)**
j. **The significant problems with the NECC facility that the FDA later found during its October 2012 inspection and as logged in its Form 483.**
k. **NECC's clean rooms were located in an old, crumbling warehouse building that shared the site with a recycling plant.**

Additional, routine internet research or inspection of the FDA website or Massachusetts Board of Pharmacy website also would have revealed the following:

a. **There had been numerous deaths and injuries resulting from contaminated products from compounding pharmacies years prior to the meningitis catastrophe of the summer of 2012. (McAteer Dep: 228-229 and Ex. 317 and Cotugno Dep: 160);**
b. **The FDA's regulatory role in overseeing compounding pharmacies was hampered by legal and jurisdictional issues. (McAteer Dep 231-33 and Cotugno Dep: 158-59);**

c. The Massachusetts Board of Pharmacy did not have the resources, training, or expertise to strictly enforce the Board's pharmacy statutes and regulations (McAteer Dep. 233-34);
d. The FDA had previously recalled two products (betamethasone and MPA) that NECC had previously manufactured prior to the outbreak (Dep. Ex. 305);
e. NECC was not a registered FDA manufacturer meaning that it did not comply Good Manufacturing Processes and that NECC had received a Form 483 in 2003-2004 and had not been inspected by the FDA since 2005. (McAteer Dep. 147-149 and Cotugno Dep 155-56);
f. The FDA had issued a warning letter to NECC which raised significant safety issues. (Dep. Ex. 306);
g. The 2009 suspension of NECC's pharmacy tech.

13. Identify all persons or entities Plaintiffs believe acted wrongfully and proximately caused or proximately contributed to cause the injuries to the Plaintiffs. For each person or entity, please describe the basis of the belief that they acted wrongfully and caused or contributed to cause the injury.

ANSWER:

Plaintiffs object to this Interrogatory to the extent that it seeks to obtain information from consulting experts or information protected by the work product doctrine. Plaintiffs are not required to disclose the opinion of any consulting or non-disclosed expert witness at this time. Plaintiffs further object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). *See e.g., In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992).

Subject to and without waiving these or any other objection, Plaintiffs rely on the Plaintiffs' Steering Committee's Master Complaint (Dkt. 545) and Plaintiffs' Steering Committee's First Amendment to Master Complaint (Dkt. 832). In addition, discovery in this litigation is in the beginning phases. Only two depositions have been taken in the MDL. Additional discovery is likely to reveal specific facts regarding who acted wrongly and caused Plaintiff's injuries.

FIRST SUPPLEMENTAL ANSWER:

Plaintiff incorporates their response to Interrogatory 11 into this interrogatory to the extent that this Interrogatory explains in detail the Defendants' liability for their improper decision to purchase products from an out-of-state compounding pharmacy with a shoddy safety record and to violate Tennessee and Massachusetts law on the ordering of pharmaceuticals from NECC.

Plaintiff further identifies the Defendants as actors that acted wrongfully and proximately caused Plaintiffs' injuries. As explained in greater detail in Interrogatory 11, Defendants should not have purchased products from NECC and their failure to even perform the most basic forms of due diligence in choosing to do business with NECC and importing NECC's products into the state of Tennessee directly and proximately caused Plaintiffs to be exposed to NECC's tainted pharmaceuticals as more fully outlined in Count III of the Second Amended Master Complaint (Dkt. No. 1719). Plaintiffs further state that Defendants knew or should have known that ordering MPA in bulk from NECC without patient-specific prescriptions violated state pharmacy regulations of Tennessee and Massachusetts that are designed to ensure and promote patient safety. Plaintiffs further state that as a "seller" of the MPA that Plaintiffs ultimately used or consumed, Defendants are liable under Tennessee's Products Liability Act for the sale of an unreasonably dangerous product or products in a defective condition as more fully outlined in Count IX of the Second Amended Master Complaint (Dkt. No. 1719).

In addition, Saint Thomas Health, Saint Thomas Network, and St. Thomas Hospital ("Saint Thomas Entities"), as part of the Saint Thomas Health system, proximately caused Plaintiffs' injuries. The Saint Thomas Entities failed to require ambulatory surgery centers and clinics that were part of the for-profit side of the Saint Thomas Health system to follow the same medication procurement rules, policies and laws as were followed by entities on the nonprofit side of the system. The Saint Thomas Entities, through the hospital's Director of Pharmacy Services Martin Kelvas, knew that purchasing compounded medications in bulk from NECC was unlawful. In addition, the Saint Thomas Entities, through Mr. Kelvas, instructed all medication procurement personnel on the non-profit side of the system not to purchase medications from compounding pharmacies. However, the Saint Thomas Entities made no effort to provide similar instructions to for-profit entities (such as the Saint Thomas Clinic) within the Saint Thomas Health system. By allowing the for-profit entities to practice at a lower level of safety and care, when procuring medications, than entities on the nonprofit side of the Saint Thomas Health system, the Saint Thomas Entities proximately caused plaintiffs' injuries.

Because NECC was a compounding pharmacy, it was foreseeable that NECC's products did not meet the strict quality standards required of FDA regulated and approved manufacturers. Given that the Defendants bear ultimate responsibility for choosing NECC as its supplier of choice and that but for this decision Plaintiffs would never have been exposed to NECC's pharmaceuticals, Plaintiffs maintain that the Defendants are the proximate cause of Plaintiffs' injuries.

Plaintiffs also identify NECC's misconduct in manufacturing tainted MPA and acting in concert with Defendants to sell MPA in bulk without patient specific prescriptions. NECC knew or should have known it lacked the capacity and skill to safely manufacture MPA in bulk and Defendants knew or should have known that NECC lacked this capacity and NECC's misconduct was readily discoverable by the Defendants had they attempted at all to investigate NECC's operations or perform even a basic review of pharmacy regulations governing the ordering of medications

from compounding pharmacies. Defendants' failure to perform even the most basic research into NECC's activities and the Defendants' decision to inject NECC's tainted products into patients without performing even the most basic research into NECC's manufacturing practices resulted in significant harm and injury to the Plaintiffs.

Plaintiffs further identify the following documents and incorporate them by reference into this interrogatory:

- **The depositions and exhibits to the depositions of the following individuals/entities:**
  - **Dr. John Culclasure**
  - **Debra Schamberg**
  - **Scott Butler**
  - **Terry Grinder**
  - **Jeff Ebel/Clint Pharmaceuticals**
  - **Martin Kelvas**
  - **Carmen Leffler**
  - **Dawn Rudolph**
  - **Dr. Dale Batchelor**
  - **Dr. Michael Schatzlein**

- **Plaintiffs' Counsel also identifies the additional documents:**
  - **The FDA's Form 483 resulting from its October 2013 inspection of the NECC's facilities in Framingham, Massachusetts;**
  - **The October 6, 2012 FDA Press Release recalling NECC's products**
  - **FDA's testing of products manufactured by NECC at NECC_FDA_00153-173;**

Dated: September 29, 2015

Respectfully submitted,

/s/ J. Gerard Stranch, IV
J. Gerard Stranch, IV
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Plaintiffs' Steering Committee and Tennessee State Chair

CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I delivered a copy of the foregoing document via U.S. Mail and email to the attorneys listed on the attached sheet.

Dated: September 29, 2015

/s/ J. Gerard Stranch, IV
J. Gerard Stranch, IV

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2014.

_____
Notary Public

My commission expires on: _____